

NIZORAL- ketoconazole shampoo
Kramer Laboratories

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Ketoconazole 1%	Anti-dandruff shampoo

Uses controls flaking, scaling and itching associated with dandruff

Warnings

For external use only

Do not use

- on scalp that is broken or inflamed
- if you are allergic to ingredients in this product

When using this product

- avoid contact with eyes
- if product gets into eyes, rinse thoroughly with water

Stop use and ask a doctor if

- rash appears
- condition worsens or does not improve in 2-4 weeks

If pregnant or breast-feeding, ask a doctor before use.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	<ul style="list-style-type: none">■ wet hair thoroughly■ apply shampoo, generously lather, rinse thoroughly. Repeat■ use every 3-4 days for up to 8 weeks or as directed by a doctor. Then use only as needed to control dandruff
children under 12 years	<ul style="list-style-type: none">■ ask a doctor

Other information

- store between 35° and 86°F (2° and 30°C)
- protect from light
- protect from freezing
- see top panel for lot number and expiration date

Inactive ingredients

acrylic acid polymer (carbomer 1342), butylated hydroxytoluene, cocamide MEA, FD&C Blue #1, fragrance, glycol distearate, polyquaternium-7, quaternium-15, sodium chloride, sodium cocoyl sarcosinate, sodium hydroxide and/or hydrochloric acid, sodium laureth sulfate, tetrasodium EDTA, water

Questions or comments?

call **1-800-824-4894**

PRINCIPAL DISPLAY PANEL

NON-PRESCRIPTION STRENGTH

NDC 55505-191-40

Nizoral®

A-D KETOCONAZOLE SHAMPOO 1%

Anti-Dandruff Shampoo

CONTROLS FLAKING, SCALING AND ITCHING

The Freedom Will Go To Your Head

7 FL OZ (200 mL)

Before use read all label information. If you have a drug reaction, contact a doctor and report it by calling or writing:

Kramer Laboratories, Inc.
233 Mt. Airy Road,
Suite 100, Basking Ridge
NJ 07920

1-800-824-4894

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Kramer Laboratories, Inc.
233 Mt. Airy Road,
Suite 100, Basking Ridge

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Made in Belgium
US Patent No. 5,456,851

USA
692133
875



NON-PRESCRIPTION STRENGTH

NDC 55505-191-40

Nizoral®

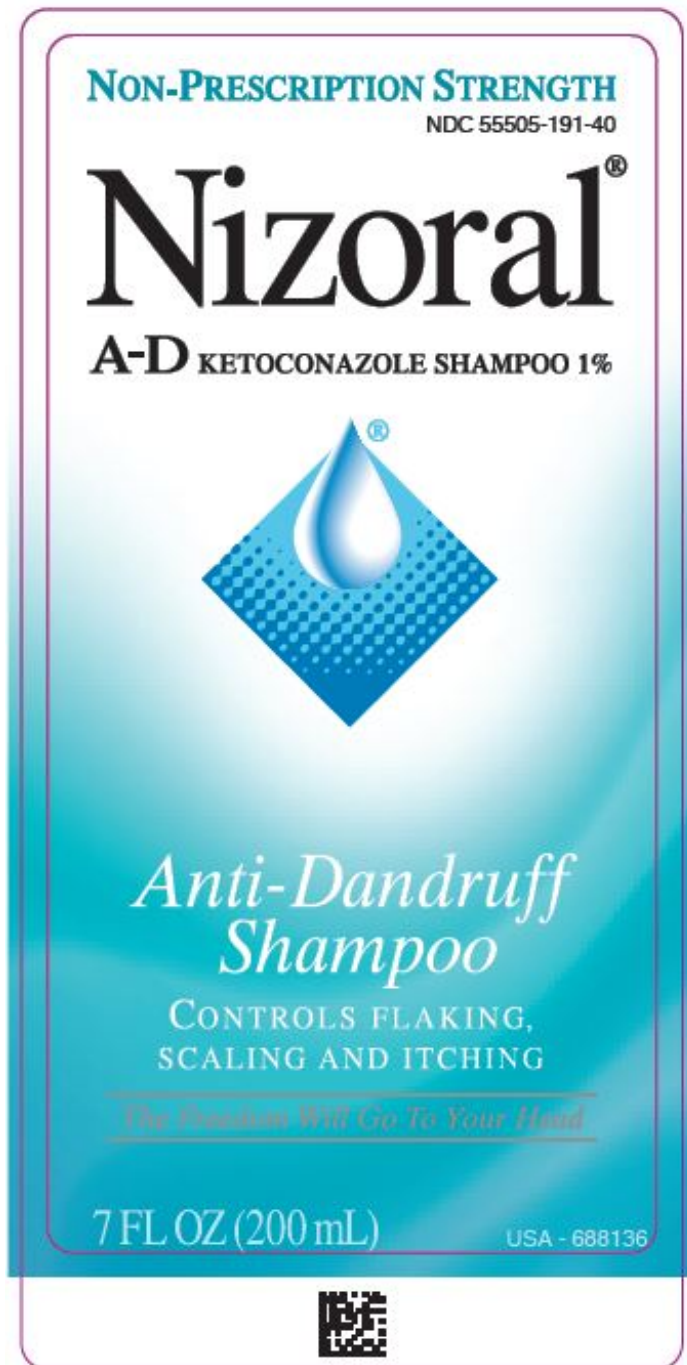
A-D KETOCONAZOLE SHAMPOO 1%

Anti-Dandruff Shampoo

CONTROLS FLAKING, SCALING AND ITCHING

7 FL OZ (200 mL)

USA - 688136



Dist. by: Kramer Laboratories, Inc.

Basking Ridge, NJ 07920 USA
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Made in Belgium
US Patent No. 5,456,851

USA - 688036

LOT

EXP

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LOT

EXP



NON-PRESCRIPTION STRENGTH

NDC 55505-191-33

Nizoral®

A-D KETOCONAZOLE SHAMPOO 1%

Anti-Dandruff Shampoo

CONTROLS FLAKING, SCALING AND ITCHING

The Freedom Will Go To Your Head

4 FL OZ (125 mL)

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NJ 07920

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Made in Belgium
US Patent No. 5,456,851

USA
688039
876



NON-PRESCRIPTION STRENGTH

NDC 55505-191-33

Nizoral®

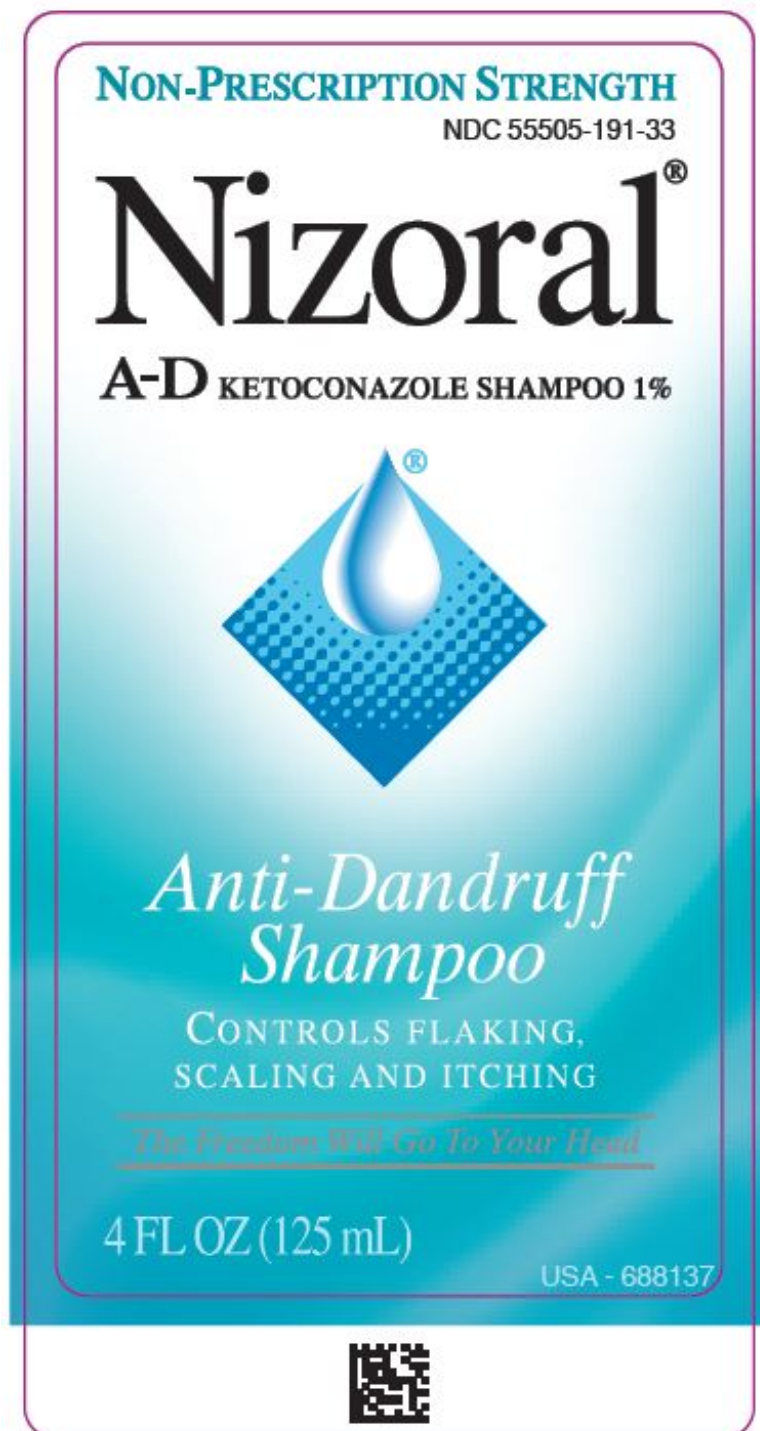
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Anti-Dandruff Shampoo

CONTROLS FLAKING, SCALING AND ITCHING

4 FL OZ (125 mL)

USA - 688137



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Questions or comments?
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Made in Belgium
US Patent No. 5,456,851

USA - 688131

LOT

EXP

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Made in Belgium
US Patent No. 5,456,851

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LOT

EXP



NIZORAL

ketoconazole shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55505-191
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
Ketoconazole (UNII: R9400W927I) (Ketoconazole - UNII:R9400W927I)			Ketoconazole	10 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked) (UNII: 809Y72KV36)				
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)				
Coco Monoethanolamide (UNII: C80684146D)				
Fd&C Blue No. 1 (UNII: H3R47K3TBD)				
Glycol Distearate (UNII: 13W7MDN21W)				
Polyquaternium-7 (70/30 Acrylamide/Dadmac; 1600000 Mw) (UNII: 0L414VCS5Y)				
Quaternium-15 (UNII: E40U03LEM0)				
Sodium Chloride (UNII: 451W47IQ8X)				
Sodium Cocoyl Sarcosinate (UNII: 1R9DUY89CZ)				
Sodium Hydroxide (UNII: 55X04QC32I)				
Hydrochloric Acid (UNII: QTT17582CB)				
Sodium Laureth-3 Sulfate (UNII: BPV390UAP0)				
Edetate Sodium (UNII: MP1J8420LU)				
Water (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-19-1-40	1 in 1 CARTON	01/07/2019	
1		200 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55505-19-1-33	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2019	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic		NDA020310	01/07/2019	

Labeler - Kramer Laboratories (122720675)

Establishment

Name	Address	ID/FEI	Business Operations
Janssen Pharmaceutica NV		370005019	analysis(55505-191) , api manufacture(55505-191) , manufacture(55505-191) , pack(55505-191)